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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,177	10/16/2003	Naomi L. Nakao	G30-016	7585

7590 07/25/2007
R. Neil Sudol
714 Colorado Avenue
Bridgeport, CT 06605-1601

EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,177

Applicant(s)

NAKAO, NAOMI L.

Examiner

Matthew J. Kasztejna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,8-13,15-24,26-28,30-32,34-37,40,41,43 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,8,10,12,13,15-24,26-28,30,34-37,40,41,43 and 45-49 is/are rejected.
- 7) ☒ Claim(s) 9,11,31 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Notice of Amendment

In response to the amendment filed April 23, 2007, amended claims 1, 3, 8, 10, 15, 22, 24, 26, 28, 30, 32, 34, 37 and 40; new claims 45-49; and canceled claims 2, 4-7, 14, 25, 29, 33, 38-39, 42 and 45 are acknowledged. The following new grounds of rejection are set forth:

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: grooves 148 and 150. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 1, 15 and 22 are objected to because of the following informalities: The mentioned claims recite, "the insertion shaft is formed *along* an outer surface". It

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appears the claims should read, "the insertion shaft is formed *having* an outer ^{surface} shaft".

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Appropriate correction is required.

Claim 32 is objected to because of the following informalities: improper claim identifier. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites the limitation "said sheath" in the second line of the claim.

There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8, 10, 12-13, 15-16, 20-24, 26-28, 30, 37, 40-41, 43, 45-46 and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,944,654 to Crawford.

In regards to claims 1, 15, 22 and 24, Crawford discloses a flexible endoscope comprising a flexible elongate insertion shaft 14, the insertion shaft is formed having an outer surface with at least one longitudinally extending channel 20 having a first transverse dimension or diameter, the channel having a longitudinally extending slot through the outer surface, the slot 24 having a second transverse dimension or width, the second transverse dimension or width being smaller than the first transverse dimension or diameter (see Col. 3, Lines 49-54), further comprising at least one closure member removably connected to the insertion shaft to close the slot, the insertion shaft being formed with a pair of opposing edges along the slot, the closure member being removably attached to the insertion shaft at the edges (see Figs. 1-2 and Col. 4, Lines 45-65).

In regards to claims 8 and 26, Crawford discloses a flexible endoscope, wherein the closure member being is an elongate strip 30 removably attached to the insertion shaft at the edges (see Figs. 2-6).

In regards to claims 10 and 30, Crawford discloses a flexible endoscope, wherein the closure member is slidably connected to the insertion shaft, the closure member being provided with an entrainment element for facilitating manipulation of the closure member to slide the closure member along the slot (see Col. 4, Lines 15-65).

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In regards to claims 12-13, 27-28 and 37, Crawford discloses a flexible endoscope, further comprising a catheter disposed in the channel (see Col. 3, Lines 15-40).

In regards to claims 16 and 40, Crawford discloses a flexible endoscope, wherein the catheter is provided at a proximal end with connectors for coupling the catheter to a source of irrigation fluid and a source of suction (see Col. 4, Lines 45-65).

In regards to claims 20 and 41, Crawford discloses a flexible endoscope, wherein the channel extends from a proximal end portion of the insertion shaft to a distal tip thereof (See Fig. 1).

In regards to claim 21, Crawford discloses a flexible endoscope, wherein the channel has a mostly circular cross-section divided by the slot, the channel being defined by a surface of the insertion member having a C-shaped cross-section (see Fig. 1).

In regards to claim 23, Crawford discloses a flexible endoscope, further comprising a sheath 50 disposed about the insertion shaft (see Fig. 4).

In regards to claim 43, Crawford discloses a flexible endoscope, wherein the channel is a one of a pair of channels formed along the outer surface of the insertion shaft, the channels being circumferentially spaced from one another (see Fig. 1).

In regards to claims 45-46 and 48-49, Crawford discloses a flexible endoscope, wherein the insertion shaft has a first outer surface and the closure member has a second outer surface, the second outer surface being smoothly continuous with the first outer surface (see Figs. 2-6).

Claims 1, 3 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,955,645 to Zeitels

In regards to claims 1, 3 and 47, Zeitels discloses a flexible endoscope comprising a flexible elongate insertion shaft 100, the insertion shaft is formed having an outer surface with at least one longitudinally extending channel 103 having a first transverse dimension or diameter, the channel having a longitudinally extending slot through the outer surface, the slot having a second transverse dimension or width, the second transverse dimension or width being smaller than the first transverse dimension or diameter (see Col. 9, Lines 19-24), further comprising at least one closure member removably connected to the insertion shaft to close the slot, the insertion shaft being formed with a pair of opposing edges along the slot, the closure member being removably attached to the insertion shaft at the edges and wherein the channel has a distal end opening and proximal end opening, the slot extending from the distal end opening to the proximal end opening, the closure member closing the slot while maintaining the distal end opening and the proximal end opening unobstructed. (see Figs. 1 and 10-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 17-19 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,944,654 to Crawford in view of U.S. Patent No. 6,585,642 to Christopher.

In regards to claims 17-19 and 34-36, Crawford discloses a flexible endoscope comprising a flexible elongate insertion shaft 14, the insertion shaft is formed having an outer surface with at least one longitudinally extending channel 20 having a first transverse dimension or diameter, the channel having a longitudinally extending slot through the outer surface, the slot 24 having a second transverse dimension or width, the second transverse dimension or width being smaller than the first transverse dimension or diameter (see Col. 3, Lines 49-54), further comprising at least one closure member removably connected to the insertion shaft to close the slot, the insertion shaft being formed with a pair of opposing edges along the slot, the closure member being removably attached to the insertion shaft at the edges (see Figs. 1-2 and Col. 4, Lines 45-65). Crawford is silent with respect to wherein at a proximal end the channel terminates at an entry port bifurcated with respect to and diverging from the shaft, further comprising a biopsy channel liner removably disposed in the channel and extending at a proximal end out of the entry port, an end cap being fitted to the liner at the entry port. Christopher discloses an analogous apparatus having a suction tube connector 44 that is attached at the proximal end of the suction tube 40 as shown in FIGS. 3 and 1. This suction tube connector 44 has an interior airway in communication with the lumen of the suction tube 40 and a vent opening 46 leading from the interior airway to the ambient atmosphere. It would have been obvious to one skilled in the art

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at the time the invention was made to include an entry port bifurcated with respect to and diverging from the shaft in the apparatus of Crawford to allow for various instruments to be passed within the channel as taught by Christopher.

Allowable Subject Matter

Claims 9, 11 and 31-32 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

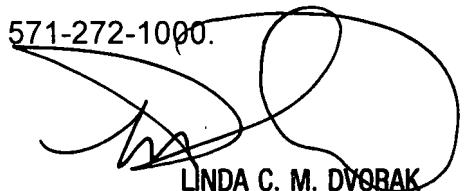
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK *mjk*

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